MAY 1 9 1999

NDA 18-603/S-020

Glaxo Wellcome Inc.
Attention: Robert S. Watson
5 Moore Drive
Research Triangle Park, NC 27709

Dear Mr. Watson:

Please refer to your May 12, 1998, special supplement: Changes Being Effected, Labeling submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zovirax (acyclovir sodium) for Injection 500 mg and 1000 mg vials.

This labeling supplement provides for changes to the **Observed During Clinical Practice** and the **Pregnancy Exposure Registry** sections of the Zovirax labeling:

1. The first paragraph under **Observed During Clinical Practice was** replaced with the following text: *In addition to adverse events reported from clinical trials, the following events have been identified during post-approval use of acyclovir (ZOVIRAX) Because they are reported voluntarily from a population of unknown size, estimates of frequency cannot be made. These events have been chosen for inclusion due to a combination of their seriousness, frequency of reporting, or potential causal connection to ZOVIRAX*

   In addition, the subsection labeled *skin* was updated to include *Erythema multiforme, rash, Stevens-Johnson syndrome, toxic epidermal necrolysis.*

2. The **Pregnancy Exposure Registry** contact number has been changed to 1-888-825-5249, ext. 39441

We have completed the review of this special supplement: Changes Being Effected, Labeling and find it to be acceptable. Accordingly, the labeling supplemental is approved effective on the date of this letter.

Please note that the above labeling changes have been superceded by the current final printed labeling (FPL) from supplemental new drug application (S-019) dated June 24, 1998. Marketing the product with FPL that is not identical to the June 24,1998 labeling may render the product misbranded and an unapproved new drug.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

Should you have any questions, please contact Melissa M. Truffa, R.Ph., Regulatory Project Manager at (301) 827-2335.

Sincerely yours,

Heidi Jolson

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